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PATENT
1662/50382
1662/1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ari Ayalon et al.
Serial No. : 09/714,351
Filed : November 16, 2000
Title : POLYMORPHIC FORM OF ATORVASTATIN
CALCIUM
Group Art Unit : 1614
Examiner : unknown

HON. COMMISSIONER OF PATENTS
AND TRADEMARKS
Washington, DC 20231

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on

Date 7/25/01 ^{sent} Atty's Reg. # 30,333

^{sent}
Atty's Signature Mary C. Kenyon
KENYON & KENYON

INFORMATION DISCLOSURE STATEMENT

SIR:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicant hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. Copies of the references are enclosed.

Statement of Relevancy

Bocan, T.M.A. et al. Atherosclerosis 1994, 111, 127-142, reports a study comparing the antiatherosclerotic effect of seven HMG CoA reductase inhibitors in rabbits. Atorvastatin was one of the HMG CoA reductase inhibitors tested in the study. The Bocan et al. article does not describe how the test samples were prepared.



Declarations of Thomas M. A. Bocan and Stephen R. Byrn: During the prosecution of U.S. Patents Nos. 5,969,156 and 5,121,461, below, the Bocan et al. article was cited against the applicants as anticipatory prior art to their claims, collectively, to atorvastatin Forms I-IV. In order to demonstrate to the Examiner that Forms I-IV were patentably distinct from the prior atorvastatin used by Bocan and coworkers, the applicants submitted a declaration of Dr. Bocan who declared that the atorvastatin he used was obtained from the Parke-Davis Research Division of Warner Lambert Company and that it had been designated as Lot XH711289. The applicants also submitted the declaration of Stephan R. Byrn. Dr. Byrn declared that on September 26, 1994 he supervised analysis of a sample of Lot XH711289 by powder X-ray diffraction and from the results concluded that it was an amorphous form of atorvastatin that he identified as "amorphous B atorvastatin." A copy of the powder X-ray diffraction pattern that was obtained from the file wrapper of U.S. Patent No. 5,121,461 is attached to the enclosed Byrn declaration.

U.S. Patent No. 4,681,893 discloses that a genus of trans-6-[2-(3- or 4-carboxamido-substituted pyrrol-1-yl)alkyl]-4-hydroxypyran-2-ones are potent inhibitors of HMG CoA reductase and useful hypolipidemic or hypocholesterolemic agents.

U.S. Patent No. 5,273,995 discloses the compound [R-(R*,R*)]-2-(4-fluorophenyl)- β,δ -dihydroxy-5-((1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid which is also known as atorvastatin.

U.S. Patent No. 5,969,156 discloses crystalline atorvastatin hydrate Form I, crystalline atorvastatin Form II and crystalline atorvastatin Form IV.

U.S. Patent No. 5,121,461 discloses crystalline atorvastatin hydrate Form III.

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U.S. Patent No. 6,087,511 discloses a process for preparing amorphous atorvastatin by dissolving crystalline Form I atorvastatin in a non-hydroxylic solvent and removing the solvent to afford amorphous atorvastatin.

Submission of this Information Disclosure Statement does not constitute an admission by the present Applicants that anything identified in the PTO-1449 form or discussed in the Statement of Relevancy is prior art to Applicants' invention.

It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due, the Commissioner is authorized to charge Deposit Account No. 11-0600 for such fees. A duplicate copy of this communication is enclosed for charging purposes.

Respectfully submitted,

KENYON & KENYON

Dated: July 25, 2001

By: Paul Johnson
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**DOCKET NO.
1662/50302SERIAL NO
09/714,351APPLICANT
ATALAN et al.FILING DATE
November 16, 2000GROUP
1614

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U. S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE*
	4,681,893	July 21, 1987	Roth			
	5,273,995	December 28, 1993	Roth			
	5,969,156	October 19, 1999	Briggs et al.			
	6,087,511	July 11, 2000	Lin et al.			
	6,121,461	September 19, 2000	McKenzie			

* - If pertinent

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
		Thomas M.A. Bocan et al. "Antiatherosclerotic activity of inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A reductase in cholesterol-fed rabbits: a biochemical and morphological evaluation", Atherosclerosis 111 (1994) pp. 127-142.
		Declaration Under Rule 132 by Thomas M.A. Bocan, dated Dec. 2, 1998, filed in U.S. Patent Application Serial No. 08/945,812; 2 pages
		Declaration Under Rule 132 by Stephen R. Byrn, dated Nov. 25, 1998, filed in U.S. Patent Application Serial No. 08/945,812; 3 pages

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	